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INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference 60083C:SDB	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).
International Application No. PCT/AU2003/001482	International Filing Date (day/month/year) 7 November 2003	Priority Date (day/month/year) 14 November 2002
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61B 17/20, A61N 1/05		
Applicant WESTERN SYDNEY AREA HEALTH SERVICE (ET AL.)		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 4 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 19 sheet(s).

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 15 June 2004	Date of completion of the report 22 November 2004
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer  MATTHEW FORWARD Telephone No. (02) 6283 2606

I. Basis of the report**1. With regard to the elements of the international application:***

- ☐ the international application as originally filed.
- ☒ the description, pages 1-6 , 14-28 as originally filed,
pages , filed with the demand,
pages 6-13a , received on 21.10.04 with the letter of 20.10.04
- ☒ the claims, pages , as originally filed,
pages , as amended (together with any statement) under Article 19,
pages , filed with the demand,
pages 29-38 , received on 21.10.04 with the letter of 20.10.04
- ☒ the drawings, pages 1/15-15/15 , as originally filed,
pages , filed with the demand,
pages , received on with the letter of
- ☐ the sequence listing part of the description:
pages , as originally filed
pages , filed with the demand
pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims 1-88	YES
	Claims	NO
inventive step (IS)	Claims 1-88	YES
	Claims	NO
Industrial applicability (IA)	Claims 1-88	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 US 6358247 B1

D2 US 6102887 A

D3 WO 1996019259 A1

D4 EP 149431 A2

D5 WO 1996007360

D6 EP 536096 B2

The amended claims define a surgical device for treating tissue, comprising: a catheter; a helical fastening needle for fastening the end of said catheter to tissue; means for deploying and retracting said helical fastening needle from and into an end of said catheter; a shaft disposed within a lumen of said catheter; and a needle-like member coupled to said shaft capable of extending from the end of the catheter through said helical fastening needle into tissue and being retracting into the end of said catheter using said shaft, said needle-like member and said helical fastening needle able to move independently of each other.

NOVELTY (N) Claims 1-88

D1 discloses surgical device for treating tissue, comprising: a catheter; a helical fastening needle (202) for fastening the end of said catheter to tissue; means for deploying and retracting said helical fastening needle from and into an end of said catheter; a shaft disposed within a lumen of said catheter; a needle-like member coupled to said shaft capable of extending from the end of the catheter through said helical fastening needle into tissue and being retracting into the end of said catheter using said shaft. D1 does not disclose needle-like member and said helical fastening needle which are able to move independently of each other. {Abstract, Fig.1-10b, column 5 line 17 - column 16 line 25}. Claims 1-88 are new and involve inventive step in view of D1.

D2 discloses a surgical device for treating tissue, comprising: a catheter; a helical fastening needle (220) for fastening the end of said catheter to tissue; means for deploying and retracting said helical fastening needle from and into an end of said catheter; a shaft disposed within a lumen of said catheter {Abstract, Fig. 1-6, column 3 line 65 - column 8 line 57}. D2 does not disclose a needle-like member coupled to said shaft capable of extending from the end of the catheter through said helical fastening needle into tissue and being retracting into the end of said catheter using said shaft. This needle-like member is obvious selection. D2 does not disclose needle-like member and said helical fastening needle which are able to move independently of each other Claims 1-88 involve inventive step in view of D2 as compared with D1 which disclose needle-like member coupled to said shaft capable of extending from the end of the catheter through said helical fastening needle into tissue and being retracting into the end of said catheter using said shaft.

Supplemental Box

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of

D3 discloses a surgical device for treating tissue, comprising: a catheter; a helical fastening needle (48) for fastening the end of said catheter to tissue; means for deploying and retracting said helical fastening needle from and into an end of said catheter; a shaft disposed within a lumen of said catheter {Abstract, Fig. 1-4, page 3 line 16 - page 7 line 33}. D3 does not disclose a needle-like member coupled to said shaft capable of extending from the end of the catheter through said helical fastening needle into tissue and being retracting into the end of said catheter using said shaft. This needle-like member is obvious selection. D3 does not disclose needle-like member and said helical fastening needle which are able to move independently of each other. Claims 1-88 involve inventive step in view of D3 as compared with D1 which disclose needle-like member coupled to said shaft capable of extending from the end of the catheter through said helical fastening needle into tissue and being retracting into the end of said catheter using said shaft.

GENERAL KNOWLEDGE

D4 discloses an electrocatheter for cardiac stimulation of the retractible active fixation type, the main characteristics of which are: the path followed at the time of anchoring causes no deformation; extraction of the wire for active anchoring to the cardiac muscle is easy; blood and organic liquids are prevented from penetrating into the stimulating head. The construction throughout with metal components ensure easy use of the catheter without alterations in the functional ability thereof, for a large number of anchoring and withdrawal operations. Claims 1-88 are new and involve inventive step in view of D4.

D5 discloses a method and apparatus for ablation of body tissue. A catheter provided with a hollow needle is employed both for mapping the location to be ablated by injection of an excitability reducing agent and for ablating tissue, employing RF energy in conjunction with an injected, conductive fluid. The hollow needle can be shaped in the form of a spring like helix intended to pierce the surface of the organ and then to penetrate into the tissue under the action of rotation imposed upon the catheter by operator. The penetration of the electrode into the tissue guarantees efficiency of ablation and prevents dispersion of energy on not targeted locations. A second ablation electrode may be present in a recessed cavity at the catheter distal end. The injection of cool or warm liquids through the helix like needle requires the liquid to be kept at the wished-for temperature along the length of the catheter. To this objective the catheter main lumen is made into three coaxial channels, the innermost of which carries the injection liquid, and the two others create a two way circuit where another heated or cooled liquid is forced to circulate to maintain the temperature of the injection liquid in the innermost tube at the distored level. Claims 1-88 are new and involve inventive step in view of D5.

D6 discloses an actively anchored electrode catheter comprising: a distal end; at least one spiral wound stimulation signal conductor (1) disposed internally of a protective insulating tubular sheath (2) provided with a free end at the distal end, the tubular sheath being surrounded at the distal end by an outer sheath forming an enlarged portion (6); an anchor terminal (3) positioned at the distal end of the electrode catheter and coaxially to the sheath (2) and provided by tip (3a). Claims 1-88 are new and involve inventive step in view of D6.

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Thus, a need clearly exists for surgical equipment that can create thermal ablation lesions using a percutaneously or endoscopically delivered intramural needle to deliver electrical energy and that allows a user to steer a catheter to the area of interest and secure the catheter firmly to the myocardium with a fixation helix. The
5 equipment must make efficient use of space to allow a maximum diameter needle to be deployed.

SUMMARY

In accordance with an aspect of the invention, a surgical device for treating
10 tissue is provided. The device comprises: a catheter; a helical fastening needle for fastening the end of the catheter to tissue; a mechanism for deploying and retracting the helical fastening needle from and into an end of the catheter; a shaft disposed within a lumen of the catheter; and a needle-like member coupled to the shaft capable of extending from the end of the catheter through the helical fastening needle into
15 tissue and being retracting into the end of the catheter using the shaft, said needle-like member and said helical fastening needle able to move independently of each other

The deploying and retracting mechanism comprise a shape memory alloy wire, and the helical fastening needle may be part of the shape memory alloy wire. Preferably, the shape memory alloy wire is made from a nickel-titanium alloy.

20 The catheter may have a second lumen, and the shape memory alloy wire may be disposed within the second lumen if the helical fastening needle is retracted. The deploying and retracting mechanism may comprise another catheter of smaller diameter coupled to the catheter, the shape memory alloy wire disposed within a lumen of the other catheter.

25 Alternatively, the deploying and retracting mechanism may comprise another catheter of small diameter disposed within the lumen of the outer catheter, the helical fastening needle coupled to the other catheter capable of rotation about the longitudinal axis of the other catheter. The needle-like member and the shaft may be disposed in the lumen of the other catheter.

30 The needle-like member may be hollow and capable of delivering a liquid to irrigate the needle-like member.

The needle-like member may comprise an electrode for delivering electromagnetic energy to thermally ablate tissue.

The needle-like member may comprise a mechanism for measuring the temperature of at least a portion of the needle-like member. The needle-like member
5 may comprise a mechanism for measuring electrical activity from and pacing nearby tissue through multiple ring-like electrodes attached to the exterior of the needle-like member.

In accordance with another aspect of the invention, a method for surgically treating tissue is provided. The method comprises: positioning a catheter
10 adjacent to the tissue, the catheter comprising a helical fastening needle for fastening the end of the catheter to tissue; deploying the helical fastening needle from the catheter into tissue to fasten the catheter to tissue using means for deploying and retracting the helical fastening needle from and into an end of the catheter; and
15 extending from the end of the catheter a needle-like member coupled to a shaft through the helical fastening needle into tissue, the needle-like member and the helical fastening needle able to move independently of each other.

The method may further comprise the step of retracting the needle-like member into the end of the catheter using the shaft.

The method may further comprise the step of retracting the helical fastening
20 needle into the end of the catheter.

The helical fastening needle may be part of the shape memory alloy wire . Preferably, the shape memory alloy wire is made from a nickel-titanium alloy. The catheter may have a second lumen, the shape memory alloy wire being disposed within the second lumen if the helical fastening needle is retracted. Alternatively,
25 another catheter of smaller diameter may be coupled to the catheter, the shape memory alloy wire being disposed within a lumen of the other catheter.

Alternatively, the deploying and retracting means comprises another catheter of small diameter disposed within a lumen of the outer catheter, the helical fastening needle coupled to the other catheter capable of rotation about the longitudinal axis of
30 the other catheter. The needle-like member and the shaft may be disposed in the lumen of the other catheter.

The needle-like member may be hollow, and the method may further comprise the step of delivering a liquid using the needle-like member to irrigate the needle-like member.

The method may further comprise the step of delivering electromagnetic
5 energy using the needle-like member to thermally ablate tissue. The method may further comprise the step of measuring the temperature of at least a portion of the needle-like member. The method may further comprise the step of measuring electrical activity from and pacing nearby tissue through multiple ring-like electrodes attached to the exterior of the needle-like member.

10 In accordance with still another aspect of the invention, a surgical device for treating tissue is provided. The device comprises: an outer elongate member with a lumen formed therethrough; an inner elongate member with a lumen formed therethrough, the inner elongate member disposed within the lumen of the outer elongate member and capable of rotation about the longitudinal axis of the inner
15 elongate member; a helical fixing member coupled at a distal end of the inner elongate member capable of extending from and retracting into the outer elongate member for screw-in type engagement with the tissue to connect a distal end of the outer elongate member adjacent to the tissue; and a needle-like member disposed within a portion of the lumen of the inner elongate member capable of being extended
20 from and retracted into an end of the elongate member using a needle shaft, the needle-like member capable of being extended concentrically through the helical fixing member into the tissue, the needle-like member and the helical fixing member able to move independently of each other.

The outer and inner elongate members may each be a catheter. Preferably, the
25 needle-like member is hollow and is capable of delivering a liquid to irrigate the electrode tissue interface. The needle-like member may be an electrode.

Alternatively, the needle-like member may have one or more ring-like electrodes disposed circumferentially about the needle-like member. The device may comprise a conductor passing through the lumen of the inner elongate member and connected
30 with the needle-like member for delivering electromagnetic energy to an electrode(s) for thermal ablation.

The helical fixing member may be made of metal.

The needle-like member may further comprise means for measuring the temperature of at least a portion of the needle-like member. Still further, the needle-like member may comprise means for measuring electrical activity from and pacing
5 the nearby tissue through multiple ring-like electrodes attached to the exterior of the needle-like member.

The device may comprise an irrigation tube located within the needle-like member, wherein the needle-like member has at least one bore for releasing irrigation liquid. Further, the device may comprise an ultrasound sensing device located within
10 the needle-like member.

The device may further comprise a valve between the outer and inner elongate members, and a valve between the inner elongate member and the needle-like member. The device may further comprise a pull wire connected to a metal ring located at the distal portion of the catheter enabling the catheter to be flexed and
15 deflexed as required.

In accordance with a further aspect of the invention, a surgical method for treating tissue is provided. The method comprises the steps of: positioning an outer elongate member with a lumen formed therethrough adjacent to the tissue to be treated; providing an inner elongate member with a lumen formed therethrough, the
20 inner elongate member disposed within the lumen of the outer elongate member and capable of rotation about the longitudinal axis of the inner elongate member; twisting a helical fixing member coupled at a distal end of the inner elongate member capable of extending from and retracting into the outer elongate member for screw-in type engagement with the tissue to connect a distal end of the outer elongate member
25 adjacent to the tissue for engagement with the tissue; and deploying into the tissue a needle-like member disposed within a portion of the lumen of the inner elongate member capable of being extended from and retracted into an end of the elongate member using a needle shaft, the needle-like member capable of being extended concentrically through the helical fixing member into the tissue, the needle-like
30 member and the helical fixing member able to move independently of each other.

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The outer and inner elongate members may each be a catheter. Preferably, the needle-like member is hollow and is capable of delivering a liquid to irrigate the electrode tissue interface. The needle-like member may be an electrode. Alternatively, the needle-like member may have one or more ring-like electrodes
5 disposed circumferentially about the needle-like member.

The method may further comprise the step of delivering the liquid via the needle-like electrode to irrigate the tissue.

The helical fixing member may be made of metal.

Preferably, the tissue is located in the heart or another organ that can be
10 reached through the vasculature.

The method may further comprise the step of measuring the temperature of at least a portion of the needle-like member.

Preferably, a valve is provided between the outer and inner elongate members, and a valve is provided between the inner elongate member and the needle-like
15 member.

Preferably, a pull wire connected to a distal metal ring is provided.

The method may further comprise the step of judging the depth that the needle-like member is to be inserted into the tissue using an ultrasound sensing device located within the needle-like member.

20 In accordance with a still further aspect of the invention, a surgical device for treating tissue is provided. The device comprises: an outer elongate member with a lumen formed therethrough; a shape memory alloy wire disposed within a further lumen and having a helical shape at one end if extended from the end of the outer elongate member for screw-in type engagement with the tissue to connect the end of
25 the outer elongate member with the tissue; a needle-like member; and an inner elongate member coupled to the needle-like member disposed within the lumen, the needle-like member capable of being extended from an end of the outer elongate member concentrically through a helical portion of the shape memory alloy wire into the tissue, the needle-like member and the shape memory alloy wire able to move
30 independently of each other.

The outer elongate member may be a catheter.

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The inner elongate member may be a catheter.

The needle-like member may be hollow and capable of delivering a liquid to irrigate the needle-like member. A conductor may be passed through the lumen of the inner elongate member and connected with an electrode of the needle-like member for
5 delivering electromagnetic energy for thermal ablation. The needle-like member further may comprise a device for measuring the temperature of at least a portion of the needle-like member.

The needle-like member further may comprise a device for measuring electrical activity from and pacing the nearby tissue through multiple ring-like
10 electrodes attached to the exterior of the needle-like member.

The device may comprise an irrigation tube located within the needle-like member, wherein the needle-like member has at least one outlet hole for releasing irrigation liquid.

The device may comprise an ultrasound sensing device located within the
15 needle-like member.

The device may comprise a valve between the outer and inner elongate members. The device may comprise a valve between the inner elongate member and the needle-like member.

The device may comprise a pull wire connected to a metal ring attached to the
20 distal portion of the outer elongate member.

The needle-like member may have an outlet adjacent an end of the needle-like member for delivering a substance to the tissue.

The device may comprise a plurality of temperature sensing or measuring devices attached to the needle-like member and arranged at intervals to enable sensing
25 or monitoring of temperature at a plurality of tissue depths.

The outer elongate member may be formed by extruding to provide the lumen and the further lumen.

The device may comprise another elongate member attached to the outer elongate member, the other elongate member having the further lumen.

30 Preferably, the shape memory alloy wire is made of a nickel-titanium alloy.

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In accordance with another aspect of the invention, a surgical method for treating tissue. The method comprises the steps of: positioning an outer elongate member with a lumen formed therethrough adjacent the tissue; extending a shape memory alloy wire disposed within a further lumen and having a helical shape at one
5 end if extended from the end of the outer elongate member for screw-in type engagement with the tissue to connect the end of the outer elongate member with the tissue; and deploying into the tissue a needle-like member coupled to an inner elongate member disposed within the lumen, the needle-like member capable of being extended from an end of the outer elongate member concentrically through a helical
10 portion of the shape memory alloy wire into the tissue, the needle-like member and the shape memory alloy wire able to move independently of each other.

The outer elongate member may be a catheter.

The inner elongate member may be a catheter.

The needle-like member may be hollow, and the method may further comprise
15 the step of delivering a liquid to irrigate the needle-like member.

A conductor may be passed through the lumen of the inner elongate member and connected with an electrode of the needle-like member, and the method may further comprise the step of delivering electromagnetic energy for thermal ablation via the electrode.

20 The method may further comprise the step of measuring the temperature of at least a portion of the needle-like member.

The method may further comprise the step of measuring electrical activity from and pacing the nearby tissue through multiple ring-like electrodes attached to the exterior of the needle-like member.

25 An irrigation tube may be located within the needle-like member, the needle-like member having at least one outlet hole for releasing irrigation liquid.

An ultrasound sensing device may be located within the needle-like member.

The needle-like member may have an outlet adjacent an end of the needle-like member, and the method may further comprise the step of delivering a substance to
30 the tissue via the outlet.

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Temperature sensing or measuring devices may be attached the needle-like member and arranged at intervals, and the method may further comprise the step of sensing or monitoring temperature at a plurality of tissue depths using the plurality of temperature sensing or measuring devices.

5 The outer elongate member may be formed by extruding to provide the lumen and the further lumen.

Another elongate member may be attached to the outer elongate member, the other elongate member having the further lumen.

Preferably, the shape memory alloy wire is made of a nickel-titanium alloy.

10

BRIEF DESCRIPTION OF THE DRAWINGS

A small number of embodiments are described herein after with reference to the drawings, in which:

15 Fig. 1 is a side elevation view of an intramural, needle-tipped catheter for treating myocardial tissue in accordance with an embodiment of the invention;

Fig. 2A is a detailed, side elevation view of the handle of the intramural, needle-tipped catheter of Fig. 1 (only a portion of the entire assembly of Fig. 1 is depicted);

20 Fig. 2B is a detailed, side elevation view of the handle of an intramural, needle-tipped catheter with an attached syringe that may be practiced in another embodiment of the invention (only a portion of the entire assembly is depicted);

Figs. 3A, 3B, 3C, 3D, and 3E are detailed, side elevation views of needle tips that can be practiced with at least one of the catheters of Fig. 1 and 2 (only a portion of the entire assembly is depicted);

25 Fig. 4 is a detailed, side elevation view of the needle tip of the catheter of Figs. 1 and 3A (electrode rings not shown) with a helical fastening member deployed in myocardial tissue;

30 Fig. 5 is a detailed, side elevation view of the needle tip of the catheter of Figs. 1, 3A and 4 with the helical fastening member and the needle-like electrode deployed in myocardial tissue;

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Figs. 6A-6D are schematic diagrams of the intramural, needle-tipped catheter in use for treating myocardial tissue in accordance with an embodiment of the invention;

5 Figs. 7A-7C are schematic diagrams illustrating deployment of an existing catheter-based system adjacent to myocardial tissue and displacement of the catheter-based system during deployment of a needle, respectively;

Fig. 8A is a perspective view of an intramural, needle-tipped catheter for treating myocardial tissue in accordance with another embodiment of the invention;

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CLAIMS

The claims defining the invention are as follows:

1. A surgical device for treating tissue, comprising:
a catheter;
a helical fastening needle for fastening the end of said catheter to tissue;
means for deploying and retracting said helical fastening needle from and into
an end of said catheter;
a shaft disposed within a lumen of said catheter; and
a needle-like member coupled to said shaft capable of extending from the end
of the catheter through said helical fastening needle into tissue and being retracting
into the end of said catheter using said shaft, said needle-like member and said helical
fastening needle able to move independently of each other.
2. The device according to claim 1, wherein said deploying and retracting
means comprise a shape memory alloy wire.
3. The device according to claim 2, wherein said helical fastening needle
is part of said shape memory alloy wire.
4. The device according to claim 2 or 3, wherein said shape memory alloy
wire is made from a nickel-titanium alloy.
5. The device according to claim 3, wherein said catheter has a second
lumen, said shape memory alloy wire being disposed within said second lumen if said
helical fastening needle is retracted.
6. The device according to claim 2, wherein said deploying and retracting
means comprises another catheter of smaller diameter coupled to said catheter, said
shape memory alloy wire disposed within a lumen of said other catheter.
7. The device according to claim 1, wherein said deploying and retracting
means comprises another catheter of small diameter disposed within a lumen of said
outer catheter, said helical fastening needle coupled to said other catheter capable of
rotation about the longitudinal axis of said other catheter.
8. The device according to claim 7, wherein said needle-like member and
said shaft are disposed in the lumen of said other catheter.
9. The device according to claim 1, wherein said needle-like member is
hollow and is capable of delivering a liquid to irrigate the needle-like member.

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10. The device according to claim 1, wherein said needle-like member comprises an electrode for delivering electromagnetic energy to thermally ablate tissue.

11. The device according to claim 10, further wherein said needle-like member comprises means for measuring the temperature of at least a portion of said needle-like member.

12. The device according to claim 10, further wherein said needle-like member comprises means for measuring electrical activity from and pacing nearby tissue through multiple ring-like electrodes attached to the exterior of said needle-like member.

13. A method for surgically treating tissue, comprising:
positioning a catheter adjacent tissue, said catheter comprising a helical fastening needle for fastening the end of said catheter to tissue;
deploying said helical fastening needle from said catheter into tissue to fasten said catheter to tissue using means for deploying and retracting said helical fastening needle from and into an end of said catheter; and
extending from the end of said catheter a needle-like member coupled to a shaft through said helical fastening needle into tissue, said needle-like member and said helical fastening needle able to move independently of each other.

14. The method according to claim 13, further comprising the step of retracting said needle-like member into the end of said catheter using said shaft.

15. The method according to claim 14, further comprising the step of retracting said helical fastening needle into the end of said catheter.

16. The method according to claim 13, wherein said helical fastening needle is part of said shape memory alloy wire.

17. The method according to claim 16, wherein said shape memory alloy wire is made from a nickel-titanium alloy.

18. The method according to claim 16, wherein said catheter has a second lumen, said shape memory alloy wire being disposed within said second lumen if said helical fastening needle is retracted.

19. The method according to claim 16, wherein another catheter of smaller diameter is coupled to said catheter, said shape memory alloy wire being disposed within a lumen of said other catheter.

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AMENDED SHEET

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20. The method according to claim 13, wherein said deploying and retracting means comprises another catheter of small diameter disposed within a lumen of said outer catheter, said helical fastening needle coupled to said other catheter capable of rotation about the longitudinal axis of said other catheter.

21. The method according to claim 20, wherein said needle-like member and said shaft are disposed in the lumen of said other catheter.

22. The method according to claim 13, wherein said needle-like member is hollow and further comprising the step of delivering a liquid using said needle-like member to irrigate said needle-like member.

23. The method according to claim 13, further comprising the step of delivering electromagnetic energy using said needle-like member to thermally ablate tissue.

24. The method according to claim 23, further comprising the step of measuring the temperature of at least a portion of said needle-like member.

25. The method according to claim 23, further comprising the step of measuring electrical activity from and pacing nearby tissue through multiple ring-like electrodes attached to the exterior of said needle-like member.

26. A surgical device for treating tissue, comprising:
an outer elongate member with a lumen formed therethrough;
an inner elongate member with a lumen formed therethrough, said inner elongate member disposed within said lumen of said outer elongate member and capable of rotation about the longitudinal axis of said inner elongate member;
a helical fixing member coupled at a distal end of said inner elongate member capable of extending from and retracting into said outer elongate member for screw-in type engagement with said tissue to connect a distal end of said outer elongate member adjacent to said tissue; and

a needle-like member disposed within a portion of said lumen of said inner elongate member capable of being extended from and retracted into an end of said elongate member using a needle shaft, said needle-like member capable of being extended concentrically through said helical fixing member into said tissue, said needle-like member and said helical fixing member able to move independently of each other.

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27. The device according to claim 26, wherein said outer elongate member is a catheter.

28. The device according to claim 26, wherein said inner elongate member is a catheter.

29. The device according to claim 26, wherein said needle-like member is hollow and is capable of delivering a liquid to irrigate the needle-like member.

30. The device according to claim 26, wherein said helical fixing member is made of metal.

31. The device according to claim 26, further comprising a conductor passing through said lumen of said inner elongate member and connected with an electrode of said needle-like member for delivering electromagnetic energy for thermal ablation.

32. The device according to claim 31, further wherein said needle-like member further comprises means for measuring the temperature of at least a portion of said needle-like member.

33. The device according to claim 31, further wherein said needle-like member further comprises means for measuring electrical activity from and pacing the nearby tissue through multiple ring-like electrodes attached to the exterior of said needle-like member.

34. The device according to claim 26, further comprising an irrigation tube located within said needle-like member, wherein said needle-like member has at least one outlet hole for releasing irrigation liquid.

35. The device according to claim 26, further comprising an ultrasound sensing device located within said needle-like member.

36. The device according to claim 26, further comprising a valve between said outer and inner elongate members.

37. The device according to claim 26, further comprising a valve between said inner elongate member and said needle-like member.

38. The device according to claim 26, further comprising a pull wire connected to a metal ring attached to the distal portion of said outer elongate member.

39. The device according to claim 26, wherein said needle-like member has an outlet adjacent an end of said needle-like member for delivering a substance to the tissue.

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40. The device according to claim 26, further comprising a plurality of temperature sensing or measuring devices attached said needle-like member and arranged at intervals to enable sensing or monitoring of temperature at a plurality of tissue depths.

41. A surgical method for treating tissue, said method comprising the steps of:

positioning an outer elongate member with a lumen formed therethrough adjacent said tissue;

providing an inner elongate member with a lumen formed therethrough, said inner elongate member disposed within said lumen of said outer elongate member and capable of rotation about the longitudinal axis of said inner elongate member;

twisting a helical fixing member coupled at a distal end of said inner elongate member capable of extending from and retracting into said outer elongate member for screw-in type engagement with said tissue to connect a distal end of said outer elongate member adjacent to said tissue for engagement with said tissue; and

deploying into said tissue a needle-like member disposed within a portion of said lumen of said inner elongate member capable of being extended from and retracted into an end of said elongate member using a needle shaft, said needle-like member capable of being extended concentrically through said helical fixing member into said tissue, said needle-like member and said helical fixing member able to move independently of each other.

42. The method according to claim 41, wherein said outer elongate member is a catheter.

43. The method according to claim 41, wherein said inner elongate member is a catheter.

44. The method according to claim 41, wherein said needle-like member is hollow and is capable of delivering a liquid to irrigate said needle-like member.

45. The method according to claim 41, further comprising the step of delivering said liquid via said needle-like member to cool the tissue electrode interface.

46. The method according to claim 41, wherein said helical fixing member is made of metal.

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47. The method according to claim 41, wherein said tissue is located in the heart or another organ that can be reached through the vasculature, a hollow organ such as the intestine or through a cavity such as but not limited to the peritoneal space or thoracic cavity.

48. The method according to claim 41, further comprising the step of delivering electromagnetic energy to said needle-like member for thermal tissue ablation via a conductor passing through said lumen and connected with an electrode of said needle-like member.

49. The method according to claim 48, further comprising the step of measuring the temperature of at least a portion of said needle-like member.

50. The method according to claim 41, wherein a valve is provided between said outer and inner elongate members.

51. The method according to claim 41, wherein a pull wire attached to a metal ring located in the distal section of said outer elongate member is provided.

52. The method according to claim 51, further comprising the step of using the pull wire to flex and deflex the outer elongate member, enabling the outer elongate member to be positioned at the region of interest.

53. The method according to claim 41, wherein a valve is provided between said inner elongate member and said needle-like member.

54. The method according to claim 41, further comprising the step of judging the depth that said needle-like member is to be inserted into said tissue using an ultrasound sensing device located within said needle-like member.

55. The method according to claim 41, wherein said positioning step involves using a pull wire attached to a distal ring to flex and deflex said outer elongate member as required.

56. The method according to claim 41, wherein said needle-like member has an outlet adjacent an end of said needle-like member for delivering a substance to the tissue.

57. The method according to claim 41, further comprising the step of sensing or monitoring temperature at a plurality of tissue depths using a plurality of temperature sensing or measuring devices attached said needle-like member and arranged at intervals.

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58. A surgical device for treating tissue, comprising:
an outer elongate member with a lumen formed therethrough;
a shape memory alloy wire disposed within a further lumen and having a helical shape at one end if extended from the end of said outer elongate member for screw-in type engagement with said tissue to connect said end of said outer elongate member with said tissue;
a needle-like member; and
an inner elongate member coupled to said needle-like member disposed within said lumen, said needle-like member capable of being extended from an end of said outer elongate member concentrically through a helical portion of said shape memory alloy wire into said tissue, said needle-like member and said shape memory alloy wire able to move independently of each other.

59. The device according to claim 58, wherein said outer elongate member is a catheter.

60. The device according to claim 58, wherein said inner elongate member is a catheter.

61. The device according to claim 58, wherein said needle-like member is hollow and is capable of delivering a liquid to irrigate the needle-like member.

62. The device according to claim 59, further comprising a conductor passing through said lumen of said inner elongate member and connected with an electrode of said needle-like member for delivering electromagnetic energy for thermal ablation.

63. The device according to claim 62, further wherein said needle-like member further comprises means for measuring the temperature of at least a portion of said needle-like member.

64. The device according to claim 62, further wherein said needle-like member further comprises means for measuring electrical activity from and pacing the nearby tissue through multiple ring-like electrodes attached to the exterior of said needle-like member.

65. The device according to claim 58, further comprising an irrigation tube located within said needle-like member, wherein said needle-like member has at least one outlet hole for releasing irrigation liquid.

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66. The device according to claim 58, further comprising an ultrasound sensing device located within said needle-like member.

67. The device according to claim 58, further comprising a valve between said outer and inner elongate members.

68. The device according to claim 58, further comprising a valve between said inner elongate member and said needle-like member.

69. The device according to claim 58, further comprising a pull wire connected to a metal ring attached to the distal portion of said outer elongate member.

70. The device according to claim 58, wherein said needle-like member has an outlet adjacent an end of said needle-like member for delivering a substance to the tissue.

71. The device according to claim 58, further comprising a plurality of temperature sensing or measuring devices attached said needle-like member and arranged at intervals to enable sensing or monitoring of temperature at a plurality of tissue depths.

72. The device according to claim 58, wherein said outer elongate member is formed by extruding to provide said lumen and said further lumen.

73. The device according to claim 58, further comprising another elongate member attached to said outer elongate member, said other elongate member having said further lumen.

74. The device according to claim 58, wherein said shape memory alloy wire is made of a nickel-titanium alloy.

75. A surgical method for treating tissue, said method comprising the steps of:

positioning an outer elongate member with a lumen formed therethrough adjacent said tissue;

extending a shape memory alloy wire disposed within a further lumen and having a helical shape at one end if extended from the end of said outer elongate member for screw-in type engagement with said tissue to connect said end of said outer elongate member with said tissue; and

deploying into said tissue a needle-like member coupled to an inner elongate member disposed within said lumen, said needle-like member capable of being extended from an end of said outer elongate member concentrically through a helical

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portion of said shape memory alloy wire into said tissue, said needle-like member and said shape memory alloy wire able to move independently of each other.

76. The method according to claim 75, wherein said outer elongate member is a catheter.

77. The method according to claim 75, wherein said inner elongate member is a catheter.

78. The method according to claim 75, wherein said needle-like member is hollow, and further comprising the step of delivering a liquid to irrigate the needle-like member.

79. The method according to claim 76, wherein a conductor passes through said lumen of said inner elongate member and is connected with an electrode of said needle-like member, and further comprising the step of delivering electromagnetic energy for thermal ablation via said electrode.

80. The method according to claim 79, further comprising the step of measuring the temperature of at least a portion of said needle-like member.

81. The method according to claim 79, further comprising the step of measuring electrical activity from and pacing the nearby tissue through multiple ring-like electrodes attached to the exterior of said needle-like member.

82. The method according to claim 75, wherein an irrigation tube is located within said needle-like member, said needle-like member having at least one outlet hole for releasing irrigation liquid.

83. The method according to claim 75, wherein an ultrasound sensing device is located within said needle-like member.

84. The method according to claim 75, wherein said needle-like member has an outlet adjacent an end of said needle-like member, and further comprising the step of delivering a substance to the tissue via said outlet.

85. The method according to claim 75, wherein a plurality of temperature sensing or measuring devices are attached said needle-like member and arranged at intervals, and further comprising the step of sensing or monitoring temperature at a plurality of tissue depths using said plurality of temperature sensing or measuring devices.

86. The method according to claim 75, wherein said outer elongate member is formed by extruding to provide said lumen and said further lumen.

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AMENDED SHEET

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87. The method according to claim 75, wherein another elongate member is attached to said outer elongate member, said other elongate member having said further lumen.

88. The method according to claim 75, wherein said shape memory alloy wire is made of a nickel-titanium alloy.